

Application Serial No. 09/762,629
Amendment dated November 23, 2004
Reply to Final Office Action of December 22, 2003

REMARKS/ARGUMENTS

Claims 74-76, and 78 have been amended. New claims 91-93 have been added. The amendments do not contain new matter. Support for the amendments can be found at page 11, lines 11-13 and page 48, lines 25-26; page 38, line 1 and page 58, lines 3-4; and page 44, line 29 through page 45, line 2. Claims 77, 79, and 80 have been cancelled. Therefore, claims 74-76, 78, and 81-91 are pending in the application. Entry of the amendment and reconsideration of the claims in view of the following Remarks is respectfully requested.

Written Description

Claims 74-90 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention.

The Examiner states that, though Applicants claim polynucleotides encoding enzymes that enhance conversion of galactose to UDP-glucose, Applicants do not adequately describe the nucleotides or methods of their use. Applicants respectfully traverse this rejection.

For purposes of meeting the requirements for Written Description, "[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." MPEP 2163. As stated in the Response to the Final Office Action filed on March 22, 2004, the identity of enzymes that convert galactose to UDP-glucose, and of the nucleotide molecules that encode them, are well known in the art (page 47, lines 10-11 of the specification). Applicants' disclosure provides the official Enzyme Commission classification numbers for each of the four enzymes disclosed as useful in the invention, thereby allowing one of skill in the art to immediately ascertain the identity of the enzyme and of its amino acid sequence via public databases. Applicants submit this information can readily be used to determine the identity of nucleotide molecules that can encode these enzymes.

In response to these arguments, the Examiner asserts that the specification does not disclose the sequence identity of a sufficient number of sequences of each of the broadly claimed genera of polynucleotides that convert galactose to UDP-glucose. Applicants respectfully disagree.

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Applicants need not explicitly describe each and every species of a claimed genus to meet the written description requirement. Applicants need only specifically describe a representative number of species within the genus. MPEP 2163 II. A.3.(a) ii). "A 'representative number of species' means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus." *Id.*

Applicants submit that the enzymes of the galactose metabolic pathway are well-known in the art. As noted above, Applicants have identified the 4 enzymes upstream of the UDP-glucose epimerase as useful in the present invention. Applicants previously provided the Examiner with printouts from public databases providing the amino acid sequences for each of these four enzymes from *E. coli*. Applicants submit that the printouts submitted by the Applicants also disclose that sequence information for the corresponding enzymes in other species is also readily available via these databases. For example, Applicants' submitted sequence printout for *E. coli* UTP-hexose-1-phosphate uridylyltransferase (EC 2.7.7.10) includes 30 hyperlinks to the corresponding sequence information for the enzyme in a wide variety of species, including human, rat, mouse, and yeast. Since the nucleotide sequences encoding this limited genus of enzymes in a variety of species are readily available, Applicants respectfully submit there is no reason of record that the specification does not provide an adequate description of a representative number of species within the genus.

During the teleconference held with the Examiner on August 2, 2004, and as discussed in the Examiner's Interview Summary, the Examiner requested the submission of information supporting the filing date of the sequence information for enzyme EC 2.7.7.10. in a public database. Applicants submit with this response printouts from a public database clearly establishing that the sequence information for *E. coli* EC 2.7.7.10 was available as of Applicants' priority date of August 11, 1998. This printout demonstrates that the sequence for this enzyme was entered in March of 1989, and last modified in November of 1997.

Applicants submit that claims 74-90 are fully described under the standard of 35 U.S.C. § 112, first paragraph, at least for the foregoing reasons. Withdrawal of the rejection is therefore requested.

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Enablement

Claims 74-90 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner asserts that the specification does not enable the transformation of all types of cells and tissues including plants, animals, or bacteria. Specifically, in the Advisory Action dated June 22, 2004, the Examiner contended it was unclear "which 'upstream enzyme' would be useful for the recited conversion of galactose to UDP-glucose, or how far upstream one can go and still be able to affect the recited conversion of galactose to UDP-glucose." Applicants respectfully traverse this rejection.

Independent claim 74 as amended recites a process for selecting transformed plant cells or plant tissue comprising transforming the cells or tissue with one or more polynucleotide encoding UDP-glucose-dependent uridyl transferase (*galT*). In the Final Office Action dated December 22, 2003, the Examiner acknowledged that the present specification is "enabling for transformation of potato and seed rape cells and tissue using the *E. coli galT* gene and selection for transformed plant material" (page 4 of the Office Action).

The Examiner also contended, however, that Applicants have not provided enablement for transformation of all types of cells and tissues. Applicants respectfully disagree. Applicants have disclosed multiple working examples that exemplify the transformation of plant cells followed by selection using the methods of the invention. Applicants specifically provide details for the transformation and selection of maize plants with a *galT* gene obtained from *E. coli*, along with details of the conditions used for the selection of the transformed maize (Example 2). Similarly, Applicants provide working examples for the transformation and selection of potato cells (Example 4) and oil seed rape (Example 5) with *galT* from *E. coli*. The disclosed working examples are notable for the diversity of species used. Maize plants, for example, are classified as monocots, while oil seed rape plants are dicots. Potato, being a tuber, is even more distinct. Thus, Applicants have provided multiple working examples of the claimed processes in plant species of widely varying biological structure and botanical classifications. Applicants submit that one of ordinary skill in the art would reasonably predict, therefore, that the method as claimed would function successfully across the genus of claimed plant cells or tissue.

Applicants submit, therefore, that the present claims are fully enabled by the specification, at least for the foregoing reasons. In light of the teachings of the specification,

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including the working examples, one of skill in the art would readily recognize that the process as claimed results in successful transformation and selection of plant cells or tissue. Applicants' disclosure has clearly demonstrated that the upstream enzyme *galT* is useful for the conversion of galactose to UDP-glucose, such that selection of transformed plant cells or plant tissue as claimed is successful. Furthermore, one of skill in the art would reasonably predict that the method as claimed would function similarly over the range of claimed plant cells and plant tissue. Withdrawal of the rejection is therefore requested.

Summary

Applicants submit that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative if prosecution may be assisted thereby.

Respectfully submitted,

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